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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/873,312 06/05/2001		06/05/2001	Masumi Oshima	01458.00007	5718	
22907	7590	10/24/2005		EXAMINER		
BANNER &			PALABRICA, RICARDO J			
SUITE 1100			ART UNIT	PAPER NUMBER		
WASHINGT	ON, DC	20001	3663			

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No	Application No.		Applicant(s)				
	Office Action Commons	09/873,312	09/873,312 OSHIMA ET AL.						
	Office Action Summary	Examiner		Art Unit					
<u>.</u>	·	Rick Palabrica		3663					
Period fo	The MAILING DATE of this communica or Reply	tion appears on the cove	er sheet with the co	orrespondence ac	idress				
WHIC - Exter after - If NO - Failu Any I	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAIL nsions of time may be available under the provisions of 3 SIX (6) MONTHS from the mailing date of this community period for reply is specified above, the maximum statute re to reply within the set or extended period for reply will reply received by the Office later than three months after the patent term adjustment. See 37 CFR 1.704(b).	LING DATE OF THIS CO 7 CFR 1.136(a). In no event, how cation. ary period will apply and will expire by statute, cause the application	OMMUNICATION vever, may a reply be time a SIX (6) MONTHS from the to become ABANDONED	By filed the mailing date of this of (35 U.S.C. § 133).	,				
Status									
1)⊠	Responsive to communication(s) filed of	on 01 September 2005							
·	This action is <b>FINAL</b> . 2b) ☐ This action is non-final.								
3)	<b>'</b>			secution as to the	e merits is				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.									
Dispositi	on of Claims	,							
4) 🛛	Claim(s) 4 and 5 is/are pending in the a	application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.								
	Claim(s) is/are allowed.								
6)⊠	6)⊠ Claim(s) <u>4 and 5</u> is/are rejected.								
7) 🗌	Claim(s) is/are objected to.								
8)[	Claim(s) are subject to restrictio	n and/or election require	ement.						
Applicati	on Papers								
9)	The specification is objected to by the E	xaminer.							
•	The drawing(s) filed on is/are: a		jected to by the E	xaminer.					
·	Applicant may not request that any objection	·	•						
	Replacement drawing sheet(s) including the	e correction is required if the	ne drawing(s) is obje	ected to. See 37 C	FR 1.121(d).				
11)	The oath or declaration is objected to by	the Examiner. Note the	e attached Office	Action or form P	ГО-152.				
Priority u	ınder 35 U.S.C. § 119		·						
	Acknowledgment is made of a claim for ☐ All b) ☐ Some * c) ☐ None of:	foreign priority under 35	5 U.S.C. § 119(a)-	(d) or (f).					
۵٫۱	a)   All b)   Some "c)   None of:  1.   Certified copies of the priority documents have been received.  2.   Certified copies of the priority documents have been received in Application No								
	3. Copies of the certified copies of the		• •		Stage				
	application from the International	•							
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Attachmen		<b>.</b> . □	1 Interview 0	DTO 440\					
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO		Interview Summary ( Paper No(s)/Mail Dat						
3) 🔀 Inforr	nation Disclosure Statement(s) (PTO-1449 or PTo r No(s)/Mail Date <u>9/1/05</u> .		Notice of Informal Pa Other:		<b>)</b> -152)				

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#### **DETAILED ACTION**

1. Applicant's 9/1/05 Amendment, which canceled claims 1-3, added new claims 4 and 5, provided a replacement drawing, and traversed the rejection of claims in the 3/1/05 Office action is acknowledged.

2. Applicant traversed the rejection of claims based on Cole (U.S. 5,378,895), Schultz et al. (U.S. 5,200,626), Harrocks et al. (U.S. 4,016,418), Gozani et al. (U.S. 5,098,640), the ground that they do not describe or suggest the two-dimensional matrix of gamma-ray energy used in the present invention. The Examiner disagrees.

Applicant's method identifies an unknown radionuclide in a sample by counting coincident gamma rays emitted by the radionuclide. This is evident from Applicant's example that conclusively identifies the presence of <sup>152</sup>Eu in a sample by the coincidence counting of the 121.8 keV and 841.6 keV gamma rays (see page 9 of the specification). The <sup>152</sup>Eu activity (i.e., counts per unit time) in the sample is then determined by direct comparison of the with a known <sup>152</sup>Eu standard.

Applicant's step of constructing a two dimensional matrix with two axes (one for each of the two coincident gamma rays) is <u>nothing more than an expedient</u> to record the data on the energies of the two coincident gammas. Clearly, if a sample contains only one or two radionuclides, Applicant's method of investigating a sample can be exercised without the aid of the so-called "two dimensional matrix" because only a few data on the gamma ray energies have to be recorded. In any case, an artisan would know that when the number of radionuclides being detected becomes unwieldy, it would be

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advantageous to plot the energies of the detected gamma rays, e.g., on a graph paper (equivalent to a two-dimensional matrix).

The Examiner's reasoning as to the artisan's capability to decide on and prepare such two-dimensional matrix, is similar to Applicant's reasoning in his traverse of 35 U.S.C. 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraph rejections in the previous Office action. For example, Applicant states in his Remarks section of the 9/1/05 Amendment:

- "Because the skilled practitioner knows how to determine an appropriate energy level for bombardment radiation, the disclosure is sufficient and enabling." (See page 8, 2nd paragraph).
- "...[A] skilled practitioner knows how to do the manipulations required to practice the claimed invention" (see page 8, 3<sup>rd</sup> paragraph).
- "Therefore, those skilled in the art can realize energy of gamma rays emitted from each radionuclide (even if the nuclide is an isotope) with reference to this and other such published data books." (See paragraph bridging pages 10 and 11).
- "However, Applicant's respectfully submit that it is within the technical knowledge of the skilled practitioner that gamma rays emitted from isotopes have different energy patterns." (See page 12, 2<sup>nd</sup> paragraph).
- "However, it is within common technical knowledge in the art that any elements can be radioactivated by using thermal neutrons having an energy level of about 30 MeV." (See page 13, 1<sup>st</sup> paragraph).

If an artisan can capably execute the above technical tasks, by Applicant's own account, the same artisan can also make a two-dimensional plot of detected coincident energies, where such need for convenience arises.

As to the limitation in claim 4, "making a peak for each radionuclide on an axis vertical to the two axes ...", this nothing more than an expedient for recording the activity data, i.e., counts associated with the coincident gamma rays. Again, where there are only one or two

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radionuclides in the sample, these counts can be written by an artisan on a sheet of paper. Where the number of radionuclides becomes unwieldy, the same artisan can easily create a plot of the counts vs. the coincident gamma ray energies.

3. Applicant traversed secondary reference, Vourvopoulos (U.S. 6,563,898 B1), on the ground that he does not disclose a two-dimensional matrix. The Examiner disagrees.

Vourvopoulos et al. has been applied to modify primary references, Cole, Schultz et al., Harrocks et al., in the rejection of claims. The teaching from Vourvopoulos et al. is with regard to comparing a measured spectrum with a known standard or library, and not on the so-called "two dimensional matrix." See section 9 of the 3/1/05 Office action.

Also, in response to Applicant's arguments against Vourvopoulos et al. individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There is neither an adequate description nor enabling disclosure as to the radioactivation of radionuclides by neutrons or gamma rays. A "radionuclide" is already radioactive and it is unclear why this radionuclide has to be made radioactive again.

5. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "highly sensitive" in claim 4 is a relative term which renders the claim indefinite. The term "highly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, the metes and bounds of the claims cannot be determined.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Cole et al., Schultz et al., Horrocks et al., or Gozani et al. in view of Vourvopoulos et al. Any one of Cole et al., Schultz et al., Horrocks et al., or Gozani et al. disclose the Applicant's claims except for the two dimensional matrix, plotting the radionuclide peak, and comparison of the radionuclide peak with a standard.

Any one of the primary references teaches coincidence counting using plural gamma ray detectors to measure a pair of coincident gamma rays, e.g., see Cole et al. at col. 2, lines 17-38; Schultz et al. at col. 2, lines 40+, col. 7, lines 17+, col. 8, lines 38-50; Horrocks et al. at Abstract and col. 7, lines 38+; Gozani et al. at col. 11, lines 22+.

Vourvopoulos et al. show it is old and advantageous in the art to compare or fit the measured spectrum or detector readings to that of a known standard or library (e.g., see col. 7, lines 2-67).

As to the matter of the two-dimensional matrix and the plotting of the peak of each radionuclide, see discussion in section 2 above.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method, as disclosed by any one of Cole et al., Schultz et al., Horrocks et al., or Gozani et al., by the teaching of Vourvopoulos et al., to compared the spectrum or detector readings with a standard, to gain the advantages thereof (i.e., accurate identification of the radionuclide and its activity), and to use a two-dimensional matrix for plotting the energies of the coincident gamma rays,

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as well as plot the radionuclide peak on an axis vertical to the two axes, to gain the advantage thereof (e.g., more efficient recording of energy and activity data) because such modification is no more than the use of well known expedients within the nuclear art.

#### Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rick Palabrica whose telephone number is 571-272-6880. The examiner can normally be reached on 6:30-5:00, Mon-Thurs.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jack Keith can be reached on 571-272-6878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RJP October 20, 2005

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